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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,760	11/10/2000	John C. Royer	5563.210-US	5635

25907 7590 12/31/2001

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EXAMINER

LOEB, BRONWEN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/31/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/710,760

Examiner

Bronwen M. Loeb

Applicant(s)

ROYER ET AL

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 79-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 79, 81 and 83-89 is/are rejected.
- 7) ☒ Claim(s) 80 and 82 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This action is in response to the amendment filed 16 October 2001 in which claims 70-78 were cancelled and new claims 79-89 were presented.

Claims 79-89 are pending.

Response to Amendment

1. All of the outstanding rejections of claims 72-78 have been withdrawn in view of Applicant's amendment canceling them.
2. New rejections, necessitated by Applicant's amendment filed 16 October 2001, are presented below.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 79, 81 and 83-89 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is based on the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description"

Requirement published in the Federal Register (Volume 64, Number 244, Pages 71427-71440). Claim 79 is drawn to an isolated trichodiene synthase comprising the amino acid sequence of SEQ ID No. 2, or a fragment thereof that has trichodiene synthase activity. This is a genus claim in terms of any fragment of SEQ ID No. 2 having trichodiene synthase activity. Claim 87 is drawn to an isolated trichodiene synthase which is a fragment of an amino acid sequence having at least 97% identity to SEQ ID No. 2 and trichodiene synthase activity. This is a genus claim in terms of any fragment having 97% identity to SEQ ID No. 2 and trichodiene synthase activity. The specification mentions only the full length trichodiene synthase from *Fusarium venenatum*. This disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all the fragments having trichodiene synthase activity based on the teachings in the specification. The specification does not teach regions or domains of the protein are essential for trichodiene synthase activity. There is no disclosure of what amino acids are in the active site, the binding pocket or the hydrophobic core of the protein. There is no structure/function relationship taught for SEQ ID No. 2. Therefore, the specification does not describe the claimed fragments in such full, clear, concise and exact terms so as to indicate that Applicant has possession of these fragments at the time of filing the present application. Thus, the written description requirement has not been satisfied.

5. Claims 87-89 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for a fragment of an amino acid sequence having at

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least 97% identity to SEQ ID No. 2 and having trichodiene synthase activity, does not reasonably provide enablement for an amino acid sequence having at least 97% identity to SEQ ID No. 2 which lacks trichodiene synthase activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Neither the specification nor the prior art teach a use for an amino acid sequence having 97% identity to SEQ ID No. 2 but which lacks trichodiene synthase activity. While 97% identity is high, it is not a guarantee of trichodiene synthase function, particularly if the differences are in the active site and/or the binding pocket and/or the hydrophobic core of the protein.

This rejection would be overcome by amending the claim to recite "An isolated functional trichodiene synthase..." and deleting the phrase "that has trichodiene synthase activity" from the end of the claim.

6. Claims 85 and 89 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 85 and 89 are drawn to an isolated trichodiene synthase obtained from a specific strain of *Fusarium venenatum*. While it is clear that the strain has been deposited at the ATCC, it is not clear that it was deposited by the instant inventors. Since the person/company who deposited the strain may withdraw it from the ATCC at any time, it is not clear the recited strain would be freely available for the one wishing to

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practice the claimed invention. Furthermore, it is not clear that the strain would be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer, or that access to the material will be available during the pendency of the patent application. Consequently, a biological deposit for patenting purposes is required.

The requirements for description and enablement may be met by depositing the cell line in a recognized depository. If the deposits are made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant or a statement by an attorney of record over his or her signature and registration number, stating that the specific material has been deposited under the Budapest Treaty and that the material will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit is not made under the Budapest Treaty, then in order to certify that the deposit meets the requirements of 37 CFR 1.801-1.809 (see Federal Register, Vol. 54, No. 161, issued August 2 1989), Applicant may provide assurance of compliance by an affidavit or declaration or by a statement by an attorney of record over his or her signature and registration number, showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

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- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
- (d) the deposit will be replaced if it should ever become inviable.

Applicant must furthermore submit a viability statement consisting of:

- (1) the name and address of the depository;
- (2) the name and address of the depositor;
- (3) the date of deposit;
- (4) the identity of the deposit and the accession number given by the depository;
- (5) the date of the viability test;
- (6) the procedures used to obtain a sample if the test is not done by the depository; and
- (7) a statement that the deposit is capable of reproduction.

A viability statement is not required for deposits made under the Budapest Treaty.

7. The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 87-89 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 87 recites "having" as a transitional phrase which is vague and indefinite as it has not been defined legally as open or closed transitional language. Amending the claim to recite "comprising" or "consisting of" as appropriate is suggested.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 79 and 87 are rejected under 35 U.S.C. §102(b) as being anticipated by Hohn et al (Molecular Plant-Microbe Interactions (1992) 5:249-256). Hohn et al teach an isolated trichodiene synthase comprising a fragment (amino acids 1-278) of SEQ ID No. 2. Absent evidence to the contrary, it is assumed that this fragment has trichodiene synthase activity. Claim 87 is a process-by product claim. As such, the patentability does not lie in the method steps ("obtained from a *Fusarium venenatum* strain"). See MPEP §2113. Hohn et al teach an isolated trichodiene synthase having an amino acid sequence which is 98.8% identical to SEQ ID No. 2. See entire document, especially Figure 2.

Conclusion

Claims 79, 81 and 83-89 are rejected. Claims 80-86, 88 and 89 are free of prior art. Claims 80 and 82 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

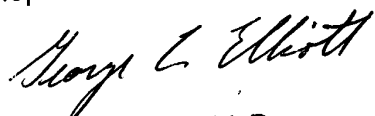
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 10:00 AM to 6:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to Dianiece Jacobs, Patent Analyst whose telephone number is (703) 305-3388.


George C. Elliott, Ph.D.
Supervisory Patent Examiner
Technology Center 1600

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Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

December 28, 2001